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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 1 1 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Michael G. Sarli
Manager Regulatory Affairs
STERIS Corporation
P.O. Box 147
St. Louis, MO 63166-0147

Subject: Amerse 2
EPA Registration No.: 1043-117
Application Date: 12/27/2010
Receipt Date: 12/30/2010

Dear Mr. Michael G. Sarli:

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with conditions.

Proposed Amendment

- Revised description from "One-Step in the Presence of Serum Germicidal Detergent" to "One-Step Germicidal Detergent"
- Addition of tagline "Interim Instrument Decontamination Solution"
- Removal of introductory paragraph and Use Directions for Cleaning and Disinfecting
- Addition of instructions to tip the 16 fl. Oz. package to fill the dispensing chamber along with a pictogram

Conditions

Revise the label as follows:

1. Delete the term "only" from the phrase "For industrial and institutional use only."
2. In the Precautionary Statements, revise the first statement and the 2nd to the last statement to read "Causes irreversible eye damage and skin burns" and "Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco, chewing gum, or using the toilet."
3. Revise the Personal Protection statement under HIV directions by deleting the term, "or," and stating "and." Personal protective clothing is not optional when cleaning up areas soiled with blood and body fluids.

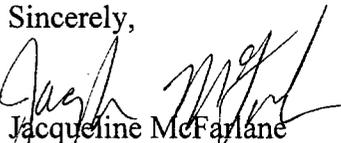
- 4. Revise the "Not recommended for prolonged..." statement under the Directions for Use by stating "Do not store instruments in the solution."
- 5. Revise the 1st and 2nd paragraphs under Virucidal by deleting the phrase "EPA-approved/proposed method."
- 6. Revise the Storage and Disposal section to read:

"Storage and Disposal: Do not contaminate water, food, or feed by storage and disposal. PESTICIDE STORAGE: Store in a cool dry area. Always store pesticides in the original container. Store away from food, pet food, feed, seed, fertilizers, and veterinary supplies. PESTICIDE DISPOSAL: Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance. CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke."

General Comments

A stamped label with conditions is enclosed for your records. Submit three (3) copies of the final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Jaclyn Carl by telephone at (703) 347-0213 or by e-mail at carl.jaclyn@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

 Jacqueline McFarlane
 Product Manager (34)
 Regulatory Management Branch II
 Antimicrobials Division (7510P)

Enclosure: Stamped label with conditions

